

# DATA EVALUATION REPORT

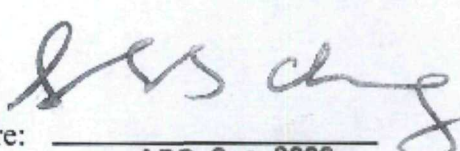
## ISOPROPANOL (FOOD CONTACT HARD SURFACE SANITIZER 6609-NS-I-66-B-1)

STUDY TYPE: PRIMARY EYE IRRITATION - RABBIT [870.2400 (81-4)]  
MRID 44977404

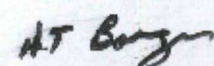
Prepared for  
Antimicrobials Division  
Office of Pesticide Programs  
U.S. Environmental Protection Agency  
1921 Jefferson Davis Highway  
Arlington, VA 22202

Prepared by  
Chemical Hazard Evaluation Group  
Toxicology and Risk Analysis Section  
Life Sciences Division  
Oak Ridge National Laboratory  
Oak Ridge, TN 37831  
Action No. K0190


Primary Reviewer:  
Susan Chang, M.S.

Signature:   
Date: APR 03 2000

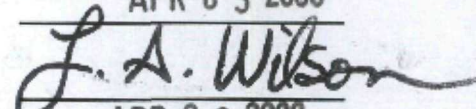
Secondary Reviewers:  
H. Tim Borges, M.T.(A.S.C.P.), Ph.D., D.A.B.T.

Signature:   
Date: APR 03 2000

Robert H. Ross, M.S., Group Leader

Signature:   
Date: APR 03 2000

Quality Assurance:  
Lee Ann Wilson, M.A.

Signature:   
Date: APR 03 2000

### Disclaimer

This review may have been altered subsequent to the contractor's signatures above.



EPA Reviewer: Wallace Powell, Ph.D. \_\_\_\_\_, Date \_\_\_\_\_  
EPA Work Assignment Manager: Nader Elkassabany, Ph.D. \_\_\_\_\_, Date \_\_\_\_\_  
Antimicrobials Division (9510C)

<b>DATA EVALUATION RECORD</b>
-------------------------------

STUDY TYPE: Primary Eye Irritation - Rabbit [OPPTS 870.2400 (§81-4)]

DP BARCODE: D261694

SUBMISSION CODE: S572362

P.C. CODE: 047501

CASE NO.: 065184

TEST MATERIAL: Food Contact Hard Surface Sanitizer 6609-NS-I-66-B-1

SYNONYMS: Not reported

CITATION: Kukulinski, M. (1999) Acute eye irritation/corrosion study. Tox Monitor Laboratories, Inc., 33 West Chicago Avenue, Oak Park, IL 60302. Study 99-0166-1, September 13, 1999. MRID 44977404. Unpublished.

SPONSOR: Nice-Pak Products, 2 Nice-Pak Park, Orangeburg, NY 10962

EXECUTIVE SUMMARY: In a primary eye irritation study (MRID 44977404) 0.1 mL of Food Contact Hard Surface Sanitizer 6609-NS-I-66-B-1 (Lot No. not reported) was instilled into the conjunctival sac of one eye of six adult male New Zealand white rabbits. The contralateral eye of all rabbits served as control. The eyes were scored for ocular irritation according to the Draize method 1, 24, 48, and 72 hours after instillation.

No corneal opacity or iritis were found on any rabbit. The test material did not induce positive conjunctival irritation during the study. The maximum mean total score was 4.3 recorded one hour after test material instillation.

**In this study, Food Contact Hard Surface Sanitizer 6609-NS-I-66-B-1 was minimally irritating and is in TOXICITY CATEGORY IV for primary eye irritation.**

This study is classified as **Acceptable/Guideline** and satisfies the subdivision F guideline requirements for a primary eye irritation study [870.2400 (§81-4)] in the rabbit.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.



## I. MATERIALS AND METHODS

A. MATERIALS1. Test material: Food Contact Hard Surface Sanitizer 6609-NS-I-66-B-1

Description: clear liquid

Lot/Batch #: not reported

Composition: not reported

2. Vehicle

None

3. Test animals

Species: rabbit

Strain: New Zealand White

Age and weight at dosing: approximately 8-10 weeks; males: 2.00-2.19 kg

Source: Kuiper Rabbitry, Gary, IN

Acclimation period: at least 5 days

Diet: Purina Rabbit Chow, *ad libitum*

Water: *ad libitum*

Housing: individually in stainless steel cages

Environmental conditions:

Temperature: not reported

Humidity: not reported

Air changes: not reported

Photoperiod: not reported

B. STUDY DESIGN AND METHODS1. In life dates

Start: August 11, 1999; end: August 14, 1999

2. Animal assignment and treatment

The test material (0.1 mL) was instilled into the conjunctival sac of one eye of six male rabbits and the eye lids held together for approximately 1 second. The contralateral eye of all rabbits served as control. The animals were scored for ocular irritation 1, 24, 48, and 72 hours after instillation according to the Draize method.

## II. RESULTS AND DISCUSSION

- A. No corneal opacity or iritis were found on any rabbit. The test material did not induce positive conjunctival irritation during the study. The maximum mean total score was 4.3 recorded at one hour after test material instillation.

This classifies the test material as minimally irritating. Food Contact Hard Surface Sanitizer 6609-NS-I-66-B-1 is in TOXICITY CATEGORY IV.

### B. DEFICIENCIES

The lot no. of the test material and environmental conditions of the animal room were not reported. These would not affect the study results.